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(71)(72) Applicant and Inventor: FERRARA DE ALMEIDA CUNHA, Paulo [BR/BR]; Rua Alagoas, 1314, Sala 715, Savassi, Belo Horizonte, MG (BR).

(74) Agent: DANNEMANN, SIEMSEN, BIGLER & IPANEMA MOREIRA; Rua Marquês de Olinda, 70, Botafogo, 22251-040 Rio de Janeiro, RJ (BR).

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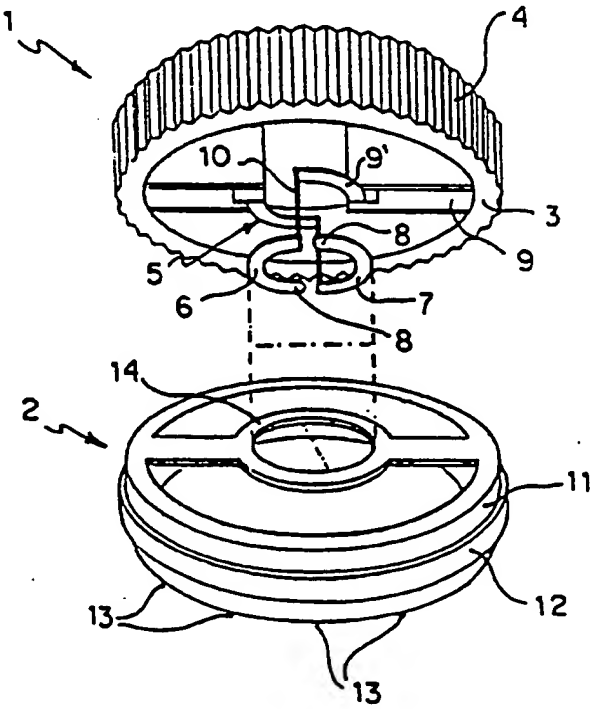
(54) Title: DEVICE AND METHOD FOR IMPLANTING AN INTRALAMELLAR RING IN THE CORRECTION OF AMETROPIAS

(57) Abstract

A device that permits implantation of an intracorneal ring for the correction of ametropias very easily and without causing alterations in the cornea is disclosed that comprises two semicircular complementary strip-like cutting members (6, 7), support means (5) for maintaining the cutting member in fixed relationship and a hand held operating member (3) associated with the support means and having a peripheral circular finger engaging surface (4). In use, two small incisions are first made in the cornea of the eye of a patient and the surgeon then, holding the operating member (3) between his fingers, presses the cutting members (6, 7) against the cornea with leading ends of the cutting members inserted into the incisions, and then rotates the device through 180°. This creates a 360° tunnel in the cornea. The device is then reverse rotated and removed, after which an intralamellar split ring (16) of silicon or the like is introduced into the tunnel using forceps. The ends of the ring are rounded to facilitate insertion and apertures (17) to facilitate manipulation during the operation.



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Title: "DEVICE AND METHOD FOR IMPLANTING AN INTRALAMELLAR RING IN THE CORRECTION OF AMETROPIAS"

FIELD OF THE INVENTION AND PRIOR ART

The present invention refers to a tunnel forming device and method for permitting the implantation of an intrlamellar ring in the cornea for the correction of ametropias.

The conception of an intracorneal ring has been developed by various authors. Published papers indicate, as one of the main difficulties, an easy and reliable technique for implanting the ring.

The techniques known so far are the "pocket discision" and the "lamellar keratectomy" by means of microkeratome. Both techniques, however, have a serious drawback, namely the interface formed at the level of the optical zone, which is detrimental to the transparency and the final visual result. Besides, the microkeratome is an expensive apparatus and requires a high degree of training, thus discouraging most surgeons from using it, especially bearing in mind the cost-benefit relationship.

SUMMARY OF THE INVENTION

The device of the present patent application overcomes this problems, enabling the intracorneal ring to be implanted very easily, besides not causing any corneal alteration. This result is achieved by forming a "tunnel" in the cornea, for implanting the ring, using a symmetrically balanced cutting arrangement.

According to the present invention a device for per-

mitting the implantation of an intralamellar ring in the cornea for the correction of ametropias, comprises:

- first and second complementary substantially semicircular strip-like cutting members, each of the cutting members having a free leading end and a supported trailing end to define a circular annular configuration with the leading end of the first cutting member adjacent but spaced from the trailing end of the second cutting member and the leading end of the second cutting member adjacent but spaced from the trailing end of the first cutting member;

- rigid cutting member support means supporting the trailing ends of the cutting members at diametrically opposite points with respect to the circular configuration; and

- manual operating means associated with the support means and having a periferal circular finger engaging surface of a diameter greater than that of the circular configuration defined by the cutting members.

The use of a device of this nature in which the tunnel forming cutting members are semicircular results in balanced resistance to rotation which permits the elimination of more complicted positioning equipment as is known in the prior art. In one embodiment of this invention, the device defined above also includes a separate base member having an annular peripheral portion supporting a radially inner guide portion defining an inner diameter substantially equal to the outer diameter of the circular configuration defined by the cutting members. Placement of the base member against the cornea permits it to be used to guide the cutter members during the tunnel forming operation.

In spite of the above, however, the device of the invention has proved to be so simple to use that the base member has been found to be unnecessary. In the preferred embodiment of the invention, therefore, the rigid support means comprise a rigid outer ring and first and second L-shaped support elements, each said element having an axially directed leg having its free end fixed to the trailing edge of a respective cutting member and a radially directed leg having its free end fixed to the rigid ring. Preferably, the manual operating means comprises a tubular part arranged to be coaxial

with the rigid outer ring, the ring being mountable over one end of the tubular part.

The device can be manufactured from any rigid, metallic or non-metallic material. Titanium is the preferred material.

In accordance with another aspect of the invention, a method of implanting an interlamellar ring in the cornea for the correction of ametropias, comprises the steps of :

a) effecting a pair of small radially oriented incisions in the cornea at two diametrically opposite locations with respect to the axis of the iris;

b) providing a tunnel forming device having two complementary substantially semicircular cutting members in rigid fixed relation with respect to each other, each having a leading end and a trailing end, the leading end of each cutting member being circumferentially spaced from, but adjacent to the trailing end of the other cutting member;

c) placing the device over the cornea with the leading end of each of the cutting memebers in a respective one of the incisions;

d) pressuring the device against the cornea and twisting it through 180° in a first direction so that the leading ends form respective semicircular tunnels in the cornea;

e) twisting the device through 180° in a second opposite direction and then removing it, whereby the cornea is formed with a circular tunnel having two diametrically opposite entrances through the pair of incisions;

f) introducing a leading end of an interlamellar ring through one of the incisions and forcing it through the tunnel until it completely fills the tunnel throughout its full extension of 360°.

The interlamellar ring comprises a still further aspect of the invention and is in the form of an extension of a transparent substantially rigid material with a substantially triangular cross section, curved to form a split ring having ends closely adjacent to each other without overlap, at least one of said ends being rounded and provided with a transverse through orifice.

BRIEF DESCRIPRION OF THE DRAWINGS

The present invention will be better understood from the following description given merely by way of example, reference being made to the accompanying drawings in which:

Figure 1 is a perspective view of a tunnel forming device according to a first embodiment of the invention;

Figure 2 illustrates the formation of a small radially directed incision in the cornea;

Figure 3 is a top view of the cornea with a pair of small radially oriented incisions in diametrically opposite locations with respect to the axis of the iris, prior to a tunnel forming operation;

Figure 4 shows the device of Figure 1 being applied to the cornea to form a tunnel of 360°;

Figure 5 shows the introduction of an intralamellar ring into a tunnel formed in the cornea by the device illustrated in Figure 1; and

Figure 6 is a perspective view of a second and presently preferred embodiment of a tunnel forming device according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 is a perspective showing of a first embodiment of a tunnel forming device for permitting the implantation of an intralamellar ring in the cornea for the correction of ametropias. The device illustrated comprises an upper operating part 1 and a lower base or guide part 2.

The operating part 1 comprises a rigid hand held ring 3 with a knurled circular outer surface region 4 for manipulation by the fingers of the surgeon. Internally, the ring is provided with a pair of supports 5 for a pair of tunnel forming cutting members 6 and 7, the supports 5 being joined to the ring 3 at diametrically opposite points. The cutting members 6 and 7 are strip-like blade members of semicircular shape, each having a trailing end attached to one of the supports 5 and a free leading end 8. The leading ends are sharpened in their thickness and rounded in their width. It will be observed that each leading end 8 is circumferenially closely spaced from the trailing end of the other of the cutting members, without any overlap. Consequently, the cutting members 6

and 7 define a circular annular configuration.

It will also be note that each support 5 comprise a first radial strut 9 having fixed thereto an arcuate part 9' substantially in the plane of the ring 3 and, integral with the latter an axially directed part 10 to which is that is connected the trailing edge of the respective cutting member 6 or 7. It is to be noted that parts 10 are parallel to and not coincident with the axis of ring 3. As a consequence, the annular tunnel formimg combination comprising the cutting members 6 and 7 lies in a plane parallel to that of ring 3 but, in Figure 1, projected a small distance below the ring.

The lower base part 2 comprises a second ring 11 having an outer annular projection 12 to facilitate handling using forceps or the like. Its axially lower (in Figure 1) end is formed with a series of small axially directed teeth 13 so that, on being pressed downwardly, it will grip against the cornea without risk of rotation. Internally ring 11 supports a ring shaped guide portion 14 having an inner surface with a diameter substantially equal to that of the outer diameter of the annular configuration defined by cutting members 6 and 7.

Figures 2 and 3 illustrate how a pair of small radially oriented incisions 15 may be made in the cornea, at diametrically opposite locations with respect to the axis of the iris, using the leading ends of cutting member 6 or 7.

It will be readily understood from Figure 4 in conjunction with the description given with respect to Figure 1, that when base part 2 is pressed against the cornea, the operating part 1 can be fitted over base part 2 with the cutting members guided in guide portion 14. The surgeon will then place the sharpened leading ends 8 of the cutting members in the respective incisions 15, apply a firm pressure to the operating part 1 and then rotate it slowly through 180° whereby the cutting members cut respective 180° tunnels in the cornea. On completion of this movement, the rotation (180°) is reversed and the device removed. At this time there is a complete (360°) circular tunnel in the cornea with two diametrically opposite entrances (the incisions 15). The surgeon then selects in a pair of forceps a suitable intralamellar ring 16 such as that illustrated in Figure 6 and

inserts it into one of the incisions 15. He then forces it through the tunnel until it virtually completes the 360°. If it proves difficult by pushing with the forceps for the front end of intralamellar ring 16 to reach the end of the tunnel, it may be reached from the other end, the forceps engaging in the transverse orifice 17 so that the ring may then be pulled to the desired position.

It should be noted that the intralamellar ring 16 is of a triangular cross section, that the ends are rounded to assist entry through the incision 15 and that each end is provided with a transverse orifice 17. Ring 17 may be made of any suitable, preferably transparent material that should be sufficiently rigid to be inserted in the tunnel formed by the device of this invention. Preferably it comprises acrylic or silicon but it may also be made of other inert materials.

Figure 6 shows a second , but presently preferred embodiment of the present invention in the form of a tunnel forming device in which there is no lower base part 2 as is illustrated in Figure 1 with respect to the first embodiment. It has been found that by increasing the axial dimension of the operating part so as to facilitate handling by the surgeon, the base or guide part is no longer necessary and in fact its absence facilitates the operation as there is one less part to be positioned correctly and removed at the end. In the case of the Figure 6 embodiment the cutting members 106 and 107 are identical to members 6 and 7 in the first embodiment and they will therefore not be further described.

The operating device 101 of Figure 6 comprises a tubular hand held member 103 having a knurled circular outer surface portion 104 for manipulation by the fingers of he surgeon. It is to be observed that the surface part 104 is at the top end of the tubular member 103 which extends further down to a lower end where there are diametrically opposite slots 118. In practise, tubular member has a length of about 2 cm and a diameter of about 2 cm in the region of the knurled surface portion 104 which has an axial extension of about 1 cm. The end of member 103 opposite that of the knurled surface is of a reduced diameter of about 1.1 cm.

The device 101 of Figure 6 also comprises a rigid

cutter part 119 in the form of a rigid outer ring 120 having an inner diameter substantially the same as the outer diameter of the lower end of tubular memeber 103 on which the ring is to be received by means of an interference fit. Ring 119 is also provided with a pair of L-shaped support 105. Each first leg 109 is radially inwardly directed, the two legs 109 lying along a diameter of ring 120. The second leg 110 of each support 115 is axially directed and supports at its lower end the trailing end of its respective cutting member 106 or 107.

When ring 120 is fitted over the lower end of tubular member, the outer ends of legs 109 are accommodated by the slots 118 in the lower end of the tubular member. This relative rotation between the tubular member and the cutter part 119.

In use, device 101 is of great simplicity although it creates a tunnel in the cornea in a manner identical to that of the Figure 1 embodiment. Having first made the two incisions 15 in the cornea, the cutter part 119 is fitted over the tubular member 103 and the surgeon holds the latter between his fingers, introduces the leading ends of cutter members 106 and 107 in the incisions 15 and pressing the device against the cornea rotates the device, exactly as in the first embodiment but without the presence of the base part 2.

The cutting members of the two embodiments have dimensions suitably within the following ranges:

Outer diameter: 3.00 to 12.00 mm
Unner diameter: 2.00 to 11.,00 mm
Width of the strip: 0.50 to 2.00 mm
Thickness: 0.10 to 0.30 mm

The hand held member and the cutter part may be made of metallic or non-metallic material. Silver and gold may be used, but the cutting members in particular should be of a relative hardness and titanium is preferred. material. It is to be noted that in both embodiments, the use two symmetrically arranged cutting members makes it extremely easy to produce a circular tunnel in the cornea since the resistance to rotation of the cutter is perfectly balanced.

CLAIMS

1. A device for permitting the implantation of an intralamellar ring in the cornea for the correction of ametropias, comprising:

- first and second complementary substantially semi-circular strip-like cutting members (6,7;106,107), each of said cutting members having a free leading end (8) and a supported trailing end to define a circular annular configuration with said leading end of said first cutting member (6;106) adjacent but spaced from said trailing end of said second cutting member (7;107) and said leading end of said second cutting member (7;107) adjacent but spaced from said trailing end of said first cutting member (6;106);

- rigid cutting member support means (5;105) supporting said trailing ends of said first and second cutting members (6,7;106,107) at diametrically opposite points with respect to said circular configuration; and

- manual operating means (3;103) associated with said support means and having a periferal circular finger engaging surface (4;104) having a diameter greater than that of said circular configuration defined by said cutting members (6,7;106,107).

2. A device according to claim 1, in which said manual operating means comprises an annular part (3;103) arranged to be coaxial with said circular configuration, and said support means comprise first and second supports (5,105) respectively connecting said trailing ends of said cutting members (6,7;106,107) to diametrically opposite regions of said annular part.

3. A device according to claim 2, in which each of said first and second supports (5;105) comprises a first portion (10;110) substantially parallel to the axis of said annular part and a second portion (9;109) substantially parallel to the plane defined by said cutting members.

4. A device according to claim 3, futher comprising a base member (2) having an annular peripheral portion (11)

supporting a radially inner guide portion (14) having an inner diameter substantially equal to the outer diameter of said circular configuration.

5. A device according to claim 5, further comprising small teeth (13) distributed around an axial end edge of said annular peripheral portion (11) for preventing rotation of said base member (2) when pressed against the cornea of a patient.

6. A device according to claim 1 in which said rigid support means comprise a rigid outer ring (120) and first and second L-shaped support elements (105), each said element having an axially directed leg (110) having its free end fixed to said trailing edge of a respective said cutting member (106,107) and a radially directed leg (109) having its free end fixed to said rigid ring (120).

7. A device according to claim 6, in which said manual operating means comprises a tubular part (103) arranged to be coaxial with said rigid outer ring (119), and further including mounting means (103,118) for mounting said ring (119) on said tubular part (103).

8. Device according to claim 7, in which said mounting means include a pair of diametrically opposite radial slots (119) in an end of said tubular part (103), said end having an outer diameter substantially the same as the inner diameter of said rigid outer ring (120), said radial slots (118) being dimensioned to accomodate said radially directed legs (109) of said L-shaped support elements (105) when said ring is fitted over said end of said tubular part.

9. Method of implanting an interlamellar ring in the cornea for the correction of ametropias, comprising the steps of :

a) effecting a pair of small radially oriented incisions in the cornea at two diametrically opposite locations with respect to the axis of the iris;

b) providing a tunnel forming device having two complementary substantially semicircular cutting members in rigid fixed relation with respect to each other, each having a leading end and a trailing end, the leading end of each of said cutting members being circumferentially spaced from, but adja-

cent to the trailing end of the other of said cutting members;

c) placing said device over the cornea with the leading end of each of the cutting memebers in a respective one of said incisions;

d) pressuring said device against the cornea and twisting it through 180° in a first direction so that said leading ends cut respective semicircular tunnels in the cornea;

e) twisting said device through 180° in a second opposite direction and then removing said device, whereby said cornea is formed with a circular tunnel having two diametrically opposite entrances through said pair of incisions;

f) introducing a leading end of an interlamellar ring through one of said incisions and forcing it through said tunnel until said ring completely fills said tunnel throughout its full extension of 360°.

10. Interlamellar ring comprising an extension of a transparent substantially rigid material with a substantially triangular cross section, curved to form a split ring (16) having ends closely adjacent to each other, at least one of said ends being rounded and provided with a transverse through orifice (17).

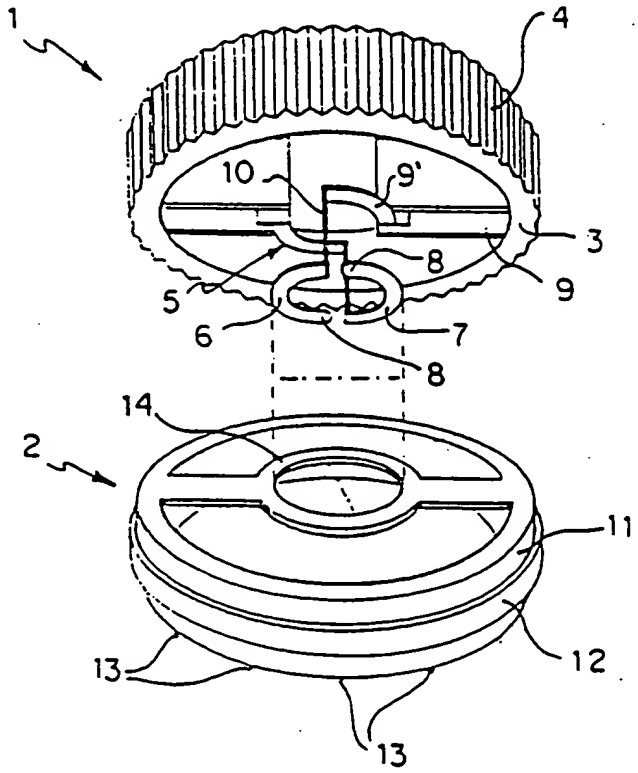


FIG. 1

FIG. 2

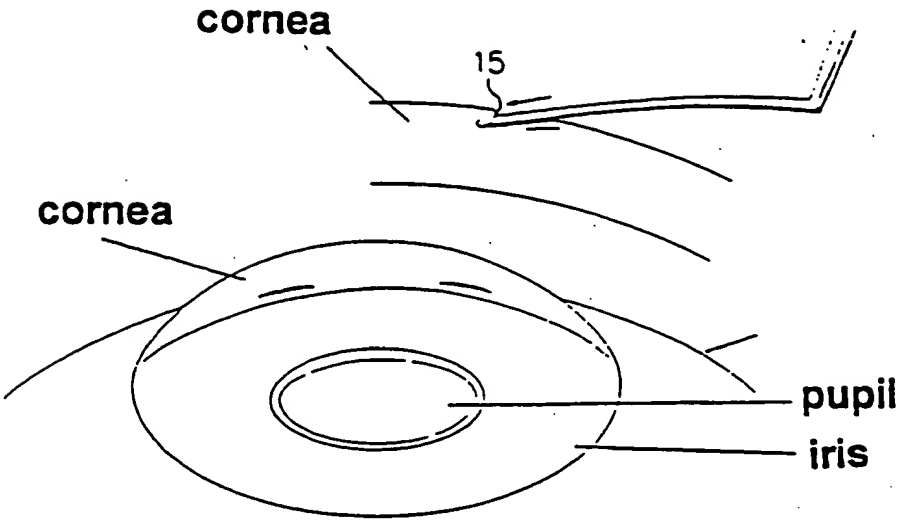
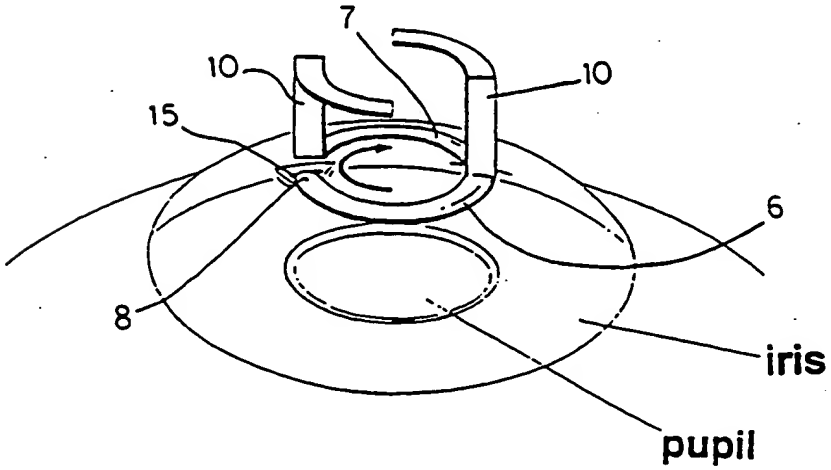


FIG. 3

FIG. 4



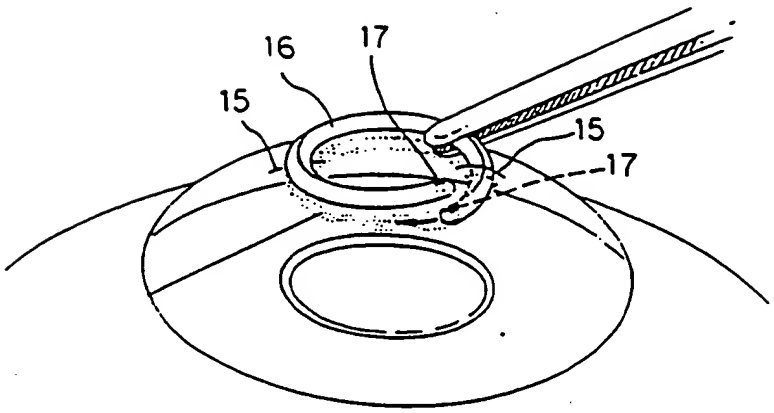
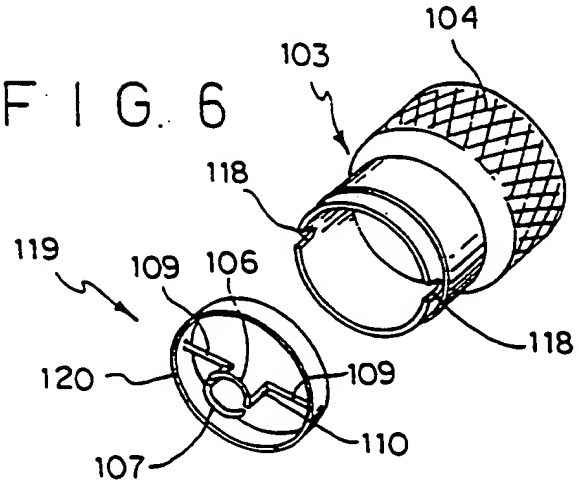


FIG. 5

FIG. 6



INTERNATIONAL SEARCH REPORT

Inte: nal Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F9/00 A61F2/14

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by cl ification symbols)
IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,93 20763 (KERAVISION) 28 October 1993 see abstract see page 17, line 25 - page 18, line 1; figures	1,2,4,5, 7 10
Y	DATABASE WPI Section PQ, Week 9151, Derwent Publications Ltd., London, GB; Class P, AN 91-37417 & SU,A,1 641 326 (ROST. MED. INST.) see abstract	1,2,4,5, 7
A	DE,A,39 36 811 (K. STORZ) 27 September 1990 see column 4, line 36 - line 39; figure 9	1

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE WPI Week 9345, Derwent Publications Ltd., London, GB; AN 93-358291 & SU,A,1 771 730 (ALMA-ATA DOCTORS TRAINING INST.) see abstract	1,10
A	WO,A,88 10096 (KERAVISION) 29 December 1988 see abstract; figures 5-7	1,4,5,7, 10
A	EP,A,0 557 128 (THE UNIVERSITY OF MIAMI) 25 August 1993 see abstract; figures 14,14 see column 7, line 31 - line 56	1,10
A	DE,A,28 11 869 (V. GEUDER) 27 September 1979 see figure 3	8
A	DE,A,36 42 521 (J.H. KRUMEICH) 23 June 1988 see column 3, line 13 - line 16; figures	5
A	WO,A,93 12735 (CHIRON INTRAOPTICS) 8 July 1993 see abstract; figure 2	10
A	US,A,4 781 187 (R.S. HERRICK) 1 November 1988 see figures 1-8	10
P,A	WO,A,94 06381 (KERAVISION) 31 March 1994 see page 10, line 15 - line 24; figures 5,6A,9A	10

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ional Application No
PCT/BR 94/00036

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9320763	28-10-93	AU-B-	4047193	18-11-93
		CA-A-	2117753	28-10-93
		CN-A-	1085071	13-04-94
DE-A-3936811	27-09-90	NONE		
WO-A-8810096	29-12-88	AU-A-	1994988	19-01-89
		EP-A-	0398874	28-11-90
		JP-T-	3500491	07-02-91
		KR-B-	9411206	29-11-94
		US-A-	4961744	09-10-90
		US-A-	5188125	23-02-93
		US-A-	5312424	17-05-94
EP-A-0557128	25-08-93	US-A-	5372580	13-12-94
		CA-A-	2089831	20-08-93
		JP-A-	6261923	20-09-94
DE-A-2811869	27-09-79	CH-A-	636765	30-06-83
		JP-A-	54127185	02-10-79
DE-A-3642521	23-06-88	US-A-	4844060	04-07-89
WO-A-9312735	08-07-93	AU-B-	3417793	28-07-93
		CA-A-	2127109	08-07-93
		EP-A-	0619724	19-10-94
US-A-4781187	01-11-88	NONE		
WO-A-9406381	31-03-94	US-A-	5323788	28-06-94
		AU-B-	5129893	12-04-94
		CN-A-	1087254	01-06-94